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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,089	04/12/2004	Signe Erickson Varner	56086CON2 (71699)	3168

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EXAMINER	
MEHTA, BHISMA	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
07/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,089	VARNER ET AL.	
	Examiner	Art Unit	
	BHISMA MEHTA	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *82-91 and 103-114* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *82-91 and 103-114* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

The phrase "that is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a)" should not be used in the declaration and should be replaced with "which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56".

Drawings

2. The drawings were received on April 15 2008. These drawings are acceptable.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Even though Applicant has indicated that the title has been amended, it does not appear that a specific amendment to amend the title has been submitted. It is suggested that the amendment to the title be given as part of an amendment to the specification in the same manner as the amendment to the abstract was made in the amendment filed April 15 2008

4. The disclosure is objected to because of the following informalities: There is no brief description of Figure 8, Figure 9A, Figure 9B, and Figure 9C. Appropriate correction is required.

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose the method with the step of inserting into a patient ear the device, where the device is inserted into the ear though an incision until the cap member abuts the incision, and where the cap member remains outside the incision and the body member resides in the patient ear. The specification also fails to disclose the method with the step of inserting the device through an incision in a patient ear by twisting or screwing the coil-shaped member in through the incision until the cap member abuts the outside of the incision, and where the body member resides in the patient ear.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 82-89, 103-109, and 112-114 are rejected under 35 U.S.C. 102(b) as being anticipated by Kelly et al (U.S. Patent No. 4,701,180).

Kelly et al disclose a method for treating a patient with the step of providing a

delivery device (10,12) comprising a body member and a cap member (14) that abuts an incision through which the device is inserted to stabilize the device once implanted and the step of inserting the device into a patient ear where the device is inserted into the ear through an incision until the cap member abuts the incision (lines 20-40 of column 3). As seen in Figure 1, the cap member remains outside of the incision and the body member resides in the patient ear. Kelly et al also disclose a therapeutic substance being administered to the patient via the body member (lines 8-31 of column 7). The body member has a helical or zig-zag shape (62) as seen in Figures 3 and 5. The device body member comprises at least five deviations from a linear path as seen in Figures 3 and 5. At least a portion of the device body member comprises a substantially zig-zag shape (Figures 3 and 5). As to claims 88 and 89, the device body comprises a polymer (lines 16-24 of column 4) or comprises a polymer that comprises a therapeutic substance to be delivered (lines 8-31 of column 7). As to claim 103, Kelly et al disclose a method for treating a patient with the step of providing a delivery device (10,12) comprising a therapeutic substance and a coil-shaped body member (62) having at least two deviations from a linear path and a cap member (14) that abuts an incision through which the device is inserted to stabilize the device once implanted and the step of inserting the device through an incision in a patient ear where the body member resides in the patient ear and the therapeutic substance is administered to the patient via the body member (lines 20-40 of column 3). Kelly et al disclose twisting or screwing the coil-shaped member (62) through the incision until the cap member abuts the outside of the incision (lines 42-64 of column 6). As to claim 104, Kelly et al

disclose the delivered substance being an antibiotic (lines 8-31 of column 7). As to claim 105, see above. As to claims 106, 107, and 114, see Figure 1. As to claim 108, 109, 112, and 113, see lines 8-31 of column 7.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claim 90 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly et al in view of Johnson (U.S. Patent No. 5,972,027).

Kelly et al disclose the method substantially as claimed. However, Kelly et al are silent on the specifics of the device comprising a shape memory material. Johnson discloses an implantable drug delivery device with a non-linear body member that can be made of nitinol, a very well known shape memory alloy of nickel-titanium (lines 39-56 of column 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Kelly et al to make the device of a shape memory material as taught by Johnson as Johnson teaches that it is well known to make an implantable device from a shape memory material to provide a bio-compatible and strong device.

10. Claim 91 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly et al in view of Rosenwald (U.S. Patent No. 4,678,466).

Kelly et al disclose the method substantially as claimed. However, Kelly et al are silent on the specifics of the length of the device being about 1.5 cm or less. Rosenwald discloses a device which is implanted in the ear where the length of the device is about 1.5 cm or less (lines 64-66 of column 9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the device of Kelly et al with a length of about 1.5 cm or less as taught by Rosenwald as Rosenwald teaches that it is well known to make a device that is to be implanted into an ear such that the device has a length of about 1.5 cm or less.

11. Claims 110 and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly et al in view of Bowman et al (U.S. Patent No. 6,397,849).

Kelly et al disclose the method substantially as claimed. However, Kelly et al are silent on the specifics of the biodegradable polymer being selected from materials such as dextran, polylactic acid, or cellulose. Bowman et al disclose implantable devices having body members comprising a biodegradable polymer such as dextran, polylactic acid, or cellulose. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use as the biodegradable polymer of Kelly et al dextran, polylactic acid, or cellulose as taught by Bowman et al as Bowman et al disclose that it is well known to use these materials for devices that are to be implanted into a patient's body.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 82-91 and 103-114 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 83-110 and 117-120 of copending Application No. 10/740,698. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a method for treating a patient comprising a delivery device comprising a body member having a coil or zig-zag shape and a cap that abuts an incision to stabilize the device, inserting the device into a patient, and wherein a therapeutic substance is administered to the patient via the body member, and wherein it would be obvious to insert the implant where desired.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

14. Applicant's arguments in lines 5-17 of page 10 filed April 15 2008 have been fully considered but they are not persuasive. The objection to the specification as failing to provide proper antecedent basis for the claimed subject matter is maintained as there is no specific disclosure of the step of inserting the device into the ear though an incision until the cap member abuts the incision and where the cap member remains outside the incision and the body member resides in the patient ear. There is also no disclosure of the step of inserting the device through an incision in a patient ear by twisting or screwing the coil-shaped member in through the incision until the cap member abuts the outside of the incision, and where the body member resides in the patient ear. Specifically, there is no disclosure of an incision being made and the device being inserted into the ear through an incision or of inserting the device through an incision in the ear. The only reference that is made to the ear is in lines 1-2 of page 24 of the specification where it is indicated that the invention "is particularly useful in other limited access regions such as the ear".

15. Applicant's arguments with respect to claims 82-91 and 104-114 have been considered but are moot in view of the new ground(s) of rejection. As to Applicant's arguments in lines 18-26 of page 11, Kelly et al do teach a method for treating a patient where the device is inserted into the ear as the area shown in Figure 1 where the device is inserted is considered to be part of the ear (lines 20-40 of column 3) and the body member has a helical or zig-zag shape (62) as seen in Figures 3 and 5. Applicant's remarks regarding the anchor and insert are unclear as Kelly et al disclose the structural

components of the device as claimed and clearly disclose the body member having a helical or zig-zag shape. Applicant's remarks regarding the device of Kelly et al being "devoid of a helical, coil, or zig-zag shaped body member for disposal within the eye" are unclear as there is no recitation in the claims of the device being disposed within the eye.

16. Applicant's arguments filed April 15 2008 have been fully considered but they are not persuasive. With regards to claim 103, Kelly et al disclose a coil-shaped body member (62) having at least two deviations from a linear path (see Figures 3 and 5).

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/
Examiner, Art Unit 3767
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